

## REMARKS

### **I. Status of the Claims**

Claims 1-24 were originally filed. Claims 2, 5, and 8-24 have been canceled. Currently, claims 1, 4, 6, and 7 are pending under examination.

Upon entry of the present amendment, claim 1 recites "wherein the taste cell specific G protein coupled receptor comprises the amino acid sequence selected from the group consisting of SEQ ID NOs:6, 7, 8, 12, 13, and 14," which correspond to the amino acid sequences of the rat, mouse, and human versions of GPCR-B3 and the rat, mouse, and human versions of GPCR-B4, respectively. The polynucleotide and amino acid sequences for rat, mouse, and human GPCR-B3 are disclosed in USSN 09/361,652 (SEQ ID NOs:1-6), whereas the polynucleotide and amino acid sequences for rat, mouse, and human GPCR-B4 are disclosed in USSN 09/361,631, now U.S. Patent No. 6,383,778 (SEQ ID NOs:1-4, 7, and 8). Since contents of both documents are incorporated in the present application by reference in the entirety (*see, e.g.,* page 11, lines 28-31, of the specification as originally filed), the present amendment is fully supported by the original disclosure and adds no new matter.

### **II. Objection to the Specification**

The Examiner suggested that the present specification be amended to include the structural and functional features of the GPCR-B4 disclosed in USSN 09/361,631. In response, the specification is amended to provide the structural and functional description of GPCR-B3 and GPCR-B4. The specification is further amended to recite the polynucleotide sequences and amino acid sequences of the rat, mouse, and human GPCR-B3 (SEQ ID NOs:3-8) and the polynucleotide sequences and amino acid sequences of rat, mouse, and human GPCR-B4 (SEQ ID NOs:9-14). A supplemental sequence listing containing SEQ ID NOs:3-14 is filed currently with this response.

The functional description of GPCR-B3 can be found, *e.g.,* on page 9, lines 27-30, of USSN 09/361,652. The functional description of GPCR-B4 can be found, *e.g.,* in column 6, lines 44-49, of U.S. Patent No. 6,383,778. The polynucleotide sequences for rat, mouse, and

human GPCR-B3 are provided in USSN 09/361,652 as SEQ ID NOs:4-6, and the amino acid sequences as SEQ ID NOs:1-3. The polynucleotide sequences for rat, mouse, and human GPCR-B4 are provided in USSN 09/361,631 (now U.S. Patent No. 6,383,778) as SEQ ID NOs:3, 4, and 8, and the amino acid sequences as SEQ ID NOs:1, 2, and 7. Because both USSN 09/361,652 and USSN 09/361,631 (now U.S. Patent No. 6,383,778) are incorporated in the present application by reference, no new matter is introduced by this amendment to the specification.

### **III. Claim Rejections**

#### **A. 35 U.S.C. §112, First Paragraph: Enablement**

Claims 1, 4, 6, and 7 were rejected under 35 U.S.C. §112, first paragraph, for alleged lack of enablement. Applicant respectfully traverses the rejection in light of the present amendment.

In the Office Action mailed June 15, 2004, the Examiner alleged inadequate enablement for the claimed invention because the specification, including USSNs incorporated therein, does not disclose all possible taste cell specific GPCRs and a skilled artisan would have to resort to trial and error experimentation to identify other taste cell specific GPCRs; on the other hand, the Examiner acknowledged on page 3 that the specification is enabling for the claimed method for identifying a compound that modulates signal transduction in taste cells, when the method comprises step (i) of contacting a cell which expresses a taste cell specific G-protein alpha subunit polypeptide and a taste cell specific G protein coupled receptor with the compound, wherein the taste cell specific G protein coupled receptor is a polypeptide that comprises SEQ ID NO:1, 2, or 7 of USSN 09/361,631, *i.e.*, the amino acid sequence for the rat, mouse, or human version of GPCR-B4.

In response, claim 1 has been amended to recite that the taste cell specific G protein coupled receptor comprises the amino acid sequence selected from the group consisting of SEQ ID NOs:6, 7, 8, 12, 13, and 14, which correspond to SEQ ID NOs:1, 2, and 3 (amino acid sequences for rat, mouse, and human GPCR-B3) of USSN 09/361,652, and SEQ ID NOs:1, 2, and 7 (amino acid sequences for rat, mouse, and human GPCR-B4) of USSN 09/361,631, now

U.S. Patent No. 6,383,778, respectively. Applicant submits that the enablement rejection is overcome in light of the amendment.

**B. 35 U.S.C. §112, First Paragraph: Written Description**

Claims 1, 4, 6, and 7 were rejected under 35 U.S.C. §112, first paragraph, for alleged inadequate written description. Applicant respectfully traverses the rejection.

In making the written description rejection, the Examiner specifically raised two issues: first, other than GPCR-B3 and GPCR-B4, there is no adequate written description for the entire genus of functional equivalents; second, the specification does not teach compounds that modulate signal transduction in taste cells, other than phenylthiocarbamide (PTC), which is disclosed in USSN 09/361,631. The Examiner further stated that the lists of tastants found in the references by Nelson and Chandrashekar, introduced by Applicant as Exhibits A-C with Applicant's response filed March 30, 2004, cannot support the conclusion that the present inventor had in his possession the claimed invention at the time when this application was filed, because these references were published after the filing date (see page 7 of the Office Action mailed June 15, 2004).

Since the amended claims now recite the taste cell specific G protein coupled receptor to be one that comprises the amino acid sequence of rat, mouse, or human GPCR-B3 or GPCR-B4, the first issue raised by the Examiner is moot.

With regard to the second issue, Applicant contends that the written description requirement does not require the present application to specifically name compounds that modulate signal transduction in taste cells and therefore can be identified using the method of this invention. To satisfy the written description requirement, a specification must describe the invention in sufficient detail so that one of skill in the art can reasonably conclude that the applicant has possession of the claimed invention. MPEP §2163. In the present case, the pending claims are not drawn to compounds that are capable of modulating signal transduction in taste cells; rather, the claims are drawn to a method that can be used to identify such compounds.

Exemplary compounds that can be identified by the claimed method are thus not directly relevant to the proper description for the claimed method.

By requiring the specification to name multiple compounds that can be actually identified using the claimed method as signaling modulators in taste cells, the Examiner appears to be expressing doubts about the operability of the claimed method and hence in essence questioning the enablement of this invention. Yet the enablement rejection raised in the previous Office Action has been indicated as withdrawn in light of the claim amendment and Applicant's arguments (see page 2 of the June 15, 2004, Office Action). Furthermore, according to the MPEP, an invention is presumed operable unless the Examiner carries the burden to show otherwise. The Examiner "must do more than merely question operability--[the Examiner] must set forth factual reasons which would lead one skilled in the art to question objective truth of the statement of operability." *In re Gaubert*, 187 USPQ 664, 666 (CCPA 1975). MPEP §2107.02 III.B. In the present case, the Examiner has not provided any evidence or objective reasons why the operability of the claimed invention is not credible. Applicant thus does not believe that it would be appropriate for the Examiner to impose a requirement to name compounds that can be identified by the claimed method, either for enablement purpose or for written description purpose.

The lists of tastants were introduced by Applicant in the response filed March 30, 2004, as a part of Applicant's argument against an enablement rejection, where the Examiner alleged that one of skill in the art would not know which compounds may potentially modulate signal transduction in taste cells and therefore may be tested using the claimed method. Therefore, these tastants were not introduced as embodiments of a genus of compounds that have been actually identified using the claimed method as signaling modulators in taste cells; rather, the tastants were introduced as evidence that one of skill in the art knew, at the time the present invention was made, how to select compounds which could be tested to identify those capable of modulating signal transduction in taste cells.

It is further noted that the Nelson *et al.* and Chandrashekar *et al.* references were introduced as evidence supporting Applicant's contention of adequate enablement. These

references, describing the work by the same research group headed by the inventor on this application, demonstrate that one of skill in the art is properly enabled to use the claimed method for identifying compounds capable of modulating signal transduction in taste cells, by screening a variety of known tastants in cells expressing a taste cell specific G-protein alpha subunit and a taste cell specific G-protein coupled receptor. Although the Nelson and Chandrashekar references were published between 2000-2002, after the filing date of the present application (January 26, 2000), it is permissible, in the case when the operability of an invention is questioned, to submit later publications for the purpose of demonstrating that the invention is indeed operable as described.

In summary, Applicant does not believe that the written description rejection was properly raised as the Examiner imposed a requirement that appears more relevant to the question of enablement. On the other hand, the instant specification fully meets the written description requirement for defining the claimed invention: a method for identifying compounds that are capable of modulating signal transduction in taste cells. As such, the withdrawal of the written description rejection is respectfully requested.

Appl. No. 09/492,028  
Amdt. dated August 18, 2004  
Reply to Office Action of June 15, 2004

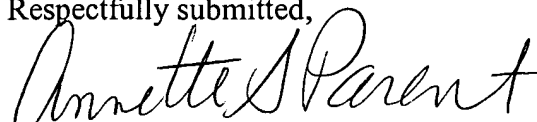
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CONCLUSION

In view of the foregoing, Applicant believes that all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 415-576-0200.

Respectfully submitted,

A handwritten signature in cursive script that reads "Annette S. Parent".

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